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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,767	02/06/2004	Jacob W. Mandema	021720-001310US	5592

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EXAMINER	
ZHOU, SHUBO	
ART UNIT	**PAPER NUMBER**
1631	

MAIL DATE	DELIVERY MODE
04/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/773,767	MANDEMA ET AL.	
	Examiner	Art Unit	
	Shubo (Joe) Zhou	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response/Amendment

Applicant's request for reconsideration and amendment filed 1/28/08 are acknowledged and the amendment is entered.

Claims 50-77 are currently pending and under examination.

Applicant's arguments filed 1/28/08 in response to the previous Office action mailed 9/24/07 have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections are either reiterated from the previous Office action or newly applied but necessitated by applicant's amendments, and constitute the complete set presently being applied to the instant application. Rejections and/or objections set forth in the previous Office action but not reiterated herein are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 55-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 50 and 75 are amended to recite at the interface, "the presented data subset is used for developing the model of the drug candidate's clinical safety, tolerability, and efficacy profile in relation to a competitor compound." While, as set forth in the previous Office action, the specification does disclose that there is a need in the art for systems for modeling the behavior of drug candidates wherein different knowledge is used for developing a model of compounds' clinical safety, tolerability, and efficacy profile in relation to the compounds' competitors, the specification does not describe an invention where in a computational system and in the context of the steps of lines 1-17, and at an interface, "the presented data subset is used for developing the model of the drug candidate's clinical safety, tolerability, and efficacy profile in relation to a competitor compound." This limitation is thus new matter.

This rejection is reiterated from the previous Office action. Applicant's arguments filed 1/28/08 have been fully considered but they are not persuasive.

First, Applicant argues that the examiner rejected the claims because "the Examiner indicated a purported lack of written description for the phrase 'the presented data subset is used for developing the model of the drug candidate's clinical safety, tolerability, and efficacy in relation to a competitor compound.'" See page 7 of 12 of the response. This is not entirely accurate because one of the major reasons for the rejection is that the specification does not provide sufficient description that this modeling process, i.e. "the presented data subset is used for developing the model of the drug candidate's clinical safety, tolerability, and efficacy profile in relation to a competitor compound," occurs at the interface.

Second, although applicant points to paragraph [0025] for description involving characterizing drug behavior in relation to different competitors, it does not specifically describe

"competitor compound," which is different from generic competitors as a competitor does not have to be a compound.

Third, while applicant cite paragraph [0041] of the specification to point to "efficacy, safety, and tolerability," the entire sentence is: Users ... will be able to compare the probability distribution for different endpoints such as biomarker, efficacy, safety, and tolerability, for different treatment strategies, for different patient populations, and for different competing products." Thus, it is clear that the phrase "efficacy, safety, and tolerability" was intended "for different treatment strategies, for different patient populations, and for different competing products," and there is no description this is for drug candidates.

In the amendment filed 1/28/08, claim 50 is amended to recite "at the interface, where the presented data subset is used for updating the model to predict the drug candidate's clinical safety, tolerability, and efficacy in relation to a competitor compound." While the specification, such as in paragraph [0053] describes updating the model, the specification does not describe that at the interface, the presented data subset is used for updating the model to predict the drug candidate's clinical safety, tolerability, and efficacy in relation to a competitor compound.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 55-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 50 and 75 recite a binary file "relevant" to a user-selection. The metes and bounds of the "relevancy" of a binary file to a user selection are not clear. One skilled in the art would not know specific criteria for determining whether a binary file is "relevant" to a user-selection and neither claims nor the specification define establishing relationships between a user-selection and a binary file. This rejection is reiterated from the Office action. Applicant argues in the 1/28/08 response that the specification provides description for this relevancy and points to Fig 5 and paragraph [0134] for support. See page 11 of 12 of the response. However, these sections do not describe a standard by which one would determine whether or not a binary file that is relevant to a user-selection.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. §1.136 (a). A shortened statutory period for response to this final action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136 (a) will be calculated from the mailing date of the advisory action. In no event, however, will the

statutory period for reply expire later than six months from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.

PRIMARY EXAMINER